



January 2011

TEST UPDATES

<http://www.focusdx.com>

This summary of test updates includes details and effective dates for new tests, changes to existing tests, and discontinued tests. For questions or additional information, please contact the Focus Diagnostics Client Services Department at (800) 445-4032. Visit our web site at www.focusdx.com.

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DISCONTINUED TESTS

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The CPT Codes provided in this document are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

**Focus Diagnostics requires a current email address to continue to provide updates to our reference laboratory menu. Please inform our Client Services Department if there is a change in staffing or email address.
Call (800) 445-4032 or email ClientServices@focusdx.com.**

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NEW TESTS

<i>Helicobacter pylori</i> Antibodies (IgG,IgA), EIA		
Effective Date:	March 7, 2011	
Unit Code:	40186	
CPT Code:	86677 (X2)	
List Price:	\$220.00	
Specimen Requirements:	1 mL (0.4 mL min.) serum	
Transport Temperature:	Room temperature	
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days	
Reference Ranges:	Negative	
Methodology:	ELISA	
Set-up Day(s):	Tuesday, Friday	
Results Available:	1-4 days	
Assay Category:	FDA/NYSDOH	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics, Inc.	
Additional Information:	<p>New test.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NEGATIVE</p> <p>Measurement of antibodies to <i>H. pylori</i> is not recommended for the diagnosis of active infection. The American College of Gastroenterology and the American Gastroenterological Association recommend either the urea breath test or the fecal antigen test for diagnosis and confirmation of eradication in cases of suspected or proven <i>H. pylori</i> infection.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	401860	<i>H. pylori</i> IgG
	401861	<i>H. pylori</i> IgA

<i>Helicobacter pylori</i> Antibodies (IgG,IgA,IgM), EIA		
Effective Date:	March 7, 2011	
Unit Code:	40187	
CPT Code:	86677 (X3)	
List Price:	\$330.00	
Specimen Requirements:	1 mL (0.6 mL min.) serum	
Transport Temperature:	Room temperature	



NEW TESTS

Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days	
Reference Ranges:	Negative	
Methodology:	ELISA	
Set-up Day(s):	Tuesday, Friday	
Results Available:	1-4 days	
Assay Category:	IgG and IgA: FDA/NYSDOH IgM: LDT/NYSDOH	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics, Inc.	
Additional Information:	<p>New test.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NEGATIVE</p> <p>Measurement of antibodies to <i>H. pylori</i> is not recommended for the diagnosis of active infection. The American College of Gastroenterology and the American Gastroenterological Association recommend either the urea breath test or the fecal antigen test for diagnosis and confirmation of eradication in cases of suspected or proven <i>H. pylori</i> infection.</p> <p>The <i>H. pylori</i> IgM assay was developed and its performance characteristics determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	401870	<i>H. pylori</i> IgG
	401871	<i>H. pylori</i> IgA
	401872	<i>H. pylori</i> IgM

<i>Helicobacter pylori</i> Antibody (IgG), EIA With Reflex to Blot	
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Effective Date:	March 7, 2011
Unit Code:	40324
CPT Code:	86677
List Price:	\$110.00
Specimen Requirements:	1 mL (0.4 mL min.) serum
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days



NEW TESTS

	Frozen: 30 days	
Reference Ranges:	Negative	
Methodology:	ELISA	
Set-up Day(s):	Tuesday, Friday	
Results Available:	1-4 days	
Assay Category:	FDA/NYSDOH	
NYSDOH Approved:	Yes	
Performing Site:	Focus Diagnostics, Inc.	
Additional Information:	<p>New test.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NEGATIVE</p> <p>Measurement of antibodies to <i>H. pylori</i> is not recommended for the diagnosis of active infection. The American College of Gastroenterology and the American Gastroenterological Association recommend either the urea breath test or the fecal antigen test for diagnosis and confirmation of eradication in cases of suspected or proven <i>H. pylori</i> infection.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	403240	<i>H. pylori</i> IgG

Meningoencephalitis Comprehensive Panel (CSF)

Effective Date:	March 21, 2011
Unit Code:	6031
CPT Code:	86603; 86644; 86645; 86651 (X2); 86652 (X2); 86653 (X2); 86654 (X2); 86658 (X17); 86695 (X2); 86696 (X2); 86710 (X2); 86727 (X2); 86735 (X2); 86765 (X2); 86787; 86788; 86789
List Price:	\$2,454.00
Specimen Requirements:	4 mL (3 mL min.) CSF
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: unacceptable Refrigerated: 7 days Frozen: 30 days
Reference Ranges:	See individual tests
Methodology:	See individual tests
Set-up Day(s):	See individual tests
Results Available:	See individual tests
Assay Category:	See individual tests
NYSDOH Approved:	See individual tests



NEW TESTS

Performing Site:	Focus Diagnostics, Inc.
Additional Information:	<p>New test.</p> <p>This profile contains the following tests:</p> <p>60215 California Encephalitis Virus Antibody Panel, IFA (CSF) 60417 Eastern Equine Encephalitis Virus Antibody, IFA (CSF) 60895 St. Louis Encephalitis Virus Antibody, IFA (CSF) 61045 Western Equine Encephalitis IgG & IgM Ab Pnl, IFA (CSF) 60625 Lymphocytic Choriomeningitis (LCM) Virus Ab, IFA (CSF) 60555 Herpes Simplex Virus 1/2 (IgG) Type-Specific Antibodies, CSF 60545 Herpes Simplex Virus (HSV) 1/2 IgM Antibody, IFA (CSF) 60100 Adenovirus Antibody, CSF 60585 Influenza Type A and B Antibodies, CSF 60675 Measles (Rubeola) IgG and IgM Antibody Panel, IFA (CSF) 60712 Mumps Antibody Panel, IFA (CSF) 61020 Varicella-Zoster Virus Antibody, CSF 60330 Coxsackie A Antibodies, CSF 60335 Coxsackie B (1-6) Antibodies, CSF 60435 Echovirus Antibodies, CSF 64600 Cytomegalovirus (CMV) IgG Antibody, ELISA (CSF) 64605 Cytomegalovirus (CMV) IgM Antibody, ELISA (CSF) 60428 West Nile Virus Antibody Panel, ELISA (CSF)</p> <p>Please contact Focus Diagnostics for CPU/Interface mapping information.</p>



TEST CHANGES

The following section contains updates to existing tests. For complete test information, contact Client Services at 800-445-4032 or visit our website at www.focusdx.com.

46570 Avian Influenza H5 Gene, QL Real-Time PCR w/rfl to A and B Culture, Rapid
46580 Avian Influenza H5 Gene, QL Real-Time PCR w/rfl to Influenza A and B RNA
46575 Avian Influenza H5 Gene, Qualitative Real-Time PCR

Effective Date:	January 1, 2011
CPT Code:	87501
Additional Information:	Update CPT code.

42699 Influenza Type A/B RT-PCR Reflex to Influenza A H1N1 (2009) RT-PCR
42684 Influenza Type A and B RNA, Qualitative Real-Time RT-PCR
46585 Influenza A H1N1 (2009) Real-Time RT-PCR

Effective Date:	January 1, 2011
CPT Code:	87502
Additional Information:	Update CPT code.

Respiratory Virus PCR Panel III

Effective Date:	January 1, 2011
Unit Code:	49990
CPT Code:	87798 (X6) 87502
Additional Information:	Update CPT code.

Respiratory Virus PCR Panel I

Effective Date:	January 1, 2011
Unit Code:	44420
CPT Code:	87798 (X5) 87502
Additional Information:	Update CPT code.

Helicobacter pylori Antibody (IgM)

Effective Date:	March 7, 2011
Unit Code:	40322
Former Test Name:	<i>Helicobacter pylori</i> IgM Antibody, ELISA
Specimen Requirements:	1 mL (0.2 mL min.) serum
Transport Temperature:	Room temperature



TEST CHANGES

Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days	
Reference Ranges:	Negative	
Assay Category:	LDT/NYSDOH	
Additional Information:	<p>Update reporting title, specimen requirements, transport temperature, stability, reference range, test code title, result flagging and always message.</p> <p>“Positive” or “Equivocal” results will be flagged “A” for abnormal.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NEGATIVE</p> <p><i>H. pylori</i> IgM testing may result in false positives. To identify active <i>H. pylori</i> infection, a urea breath test or stool antigen test should be considered if clinically indicated.</p> <p>This test was developed and its performance characteristics determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	4032	<i>H. pylori</i> IgM

Helicobacter pylori Antibody (IgG), EIA

Effective Date:	March 7, 2011
Unit Code:	40325
Former Test Name:	<i>Helicobacter pylori</i> IgG Antibody, ELISA
Specimen Requirements:	1 mL (0.2 mL min.) serum
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	Negative
Additional Information:	<p>Update reporting title, specimen requirements, transport temperature, stability, reference range, test code title, result flagging and always message.</p> <p>“Positive” or “Equivocal” results will be flagged “A” for abnormal.</p> <p>Always message will be:</p>



TEST CHANGES

	<p>REFERENCE RANGE: NEGATIVE</p> <p>Measurement of antibodies to <i>H. pylori</i> is not recommended for the diagnosis of active infection. The American College of Gastroenterology and the American Gastroenterological Association recommend either the urea breath test or the fecal antigen test for diagnosis and confirmation of eradication in cases of suspected or proven <i>H. pylori</i> infection.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	4720	<i>H. pylori</i> IgG

Helicobacter pylori Antibody (IgA), EIA

Effective Date:	March 7, 2011	
Unit Code:	40328	
Former Test Name:	<i>Helicobacter pylori</i> IgA Antibody, ELISA	
Specimen Requirements:	1 mL (0.2 mL min.) serum	
Transport Temperature:	Room temperature	
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days	
Reference Ranges:	Negative	
Assay Category:	FDA/NYSDOH	
Additional Information:	<p>Update reporting title, specimen requirements, transport temperature, stability, reference range, test code title, result flagging and always message.</p> <p>“Positive” or “Equivocal” results will be flagged “A” for abnormal.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NEGATIVE</p> <p>Measurement of antibodies to <i>H. pylori</i> is not recommended for the diagnosis of active infection. The American College of Gastroenterology and the American Gastroenterological Association recommend either the urea breath test or the fecal antigen test for diagnosis and confirmation of eradication in cases of suspected or proven <i>H. pylori</i> infection.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	4723	<i>H. pylori</i> IgA



TEST CHANGES

Echinococcus Antibody (IgG)	
Effective Date:	March 14, 2011
Unit Code:	40430
Reference Ranges:	Negative
Assay Category:	FDA/NYSDOH
Additional Information:	<p>Update reference range, assay category, result flagging and always message.</p> <p>“Positive” results will be flagged “A” for abnormal.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NEGATIVE</p> <p>Detection of serum antibodies to Echinococcus plays an important role in the diagnosis of hydatid disease, since infected individuals do not exhibit fecal shedding of Echinococcus eggs. The frequency of a positive result for serum antibodies may persist for years after cyst removal. Serologic crossreactivity between Echinococcus and Cysticercus may occur.</p>

Entamoeba histolytica IgG, ELISA	
Effective Date:	March 14, 2011
Unit Code:	40105
Reference Ranges:	Negative
Additional Information:	<p>Update test code name, reference range, result flagging and always message.</p> <p>“Positive” results will be flagged “A” for abnormal.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NEGATIVE</p> <p>Serologic studies may be helpful in the diagnosis of invasive intestinal and extraintestinal amebiasis. Eighty-five percent of patients with biopsy-proven invasive intestinal amebiasis are positive for E. histolytica IgG and over 95% of patients with extraintestinal amebiasis are positive. Sera may remain positive 6-18 months following invasive disease. Asymptomatic carriers of E. histolytica cysts are usually negative for E. histolytica IgG.</p>



TEST CHANGES

CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	4500	<i>E. histolytica</i> IgG

Trichinella IgG Antibody, ELISA

Effective Date:	March 14, 2011	
Unit Code:	40990	
Transport Temperature:	Room temperature	
Specimen Stability:	Room temperature - 7 days Refrigerated - 14 days Frozen - 30 days	
Reference Ranges:	Negative	
Additional Information:	<p>Update test code name, transport temperature, stability, reference range and always message.</p> <p>“Positive” results will be flagged “A” for abnormal.</p> <p>Always message will be:</p> <p>REFERENCE RANGE: NEGATIVE</p> <p>The Trichinella IgG ELISA employs an excretory- secretory antigen to reduce nonspecific reactivity; however, crossreactivity with other parasite antigens (e.g., strongyloides, filarial, malaria) may occur. The assay should be considered a screening test for Trichinella exposure; diagnosis of trichinosis requires a compatible patient history and supporting pathologic findings.</p>	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	4400	Trichinella IgG



TEST CHANGES

6405 Encephalitis Antibody Panel (CSF)
4055 Herpes Simplex Virus (HSV) Antibody Panel, ACIF/IFA (CSF)
6015 Meningoencephalitis (Encephalitis) Panel (CSF)

Effective Date:	March 21, 2011
Additional Information:	<p>Update components in profiles.</p> <p>Unit code 60524 Herpes Simplex Virus (HSV) 1/2 Antibody, ACIF (CSF) will be removed from these profiles.</p> <p>Unit code 60555 Herpes Simplex Virus 1/2 (IgG) Type-specific Antibodies, CSF will be added to these profiles.</p> <p>Please contact Focus Diagnostics for CPU/Interface mapping information.</p>



DISCONTINUED TESTS

***Helicobacter pylori* IgG and IgA Antibody, ELISA**

Effective Date:	March 7, 2011
Unit Code:	4030
Additional Information:	This test will be discontinued. The recommended alternative is 40186 <i>Helicobacter pylori</i> Antibodies (IgG,IgA), EIA.

***Helicobacter pylori* IgG, IgA, and IgM Antibody Panel, ELISA**

Effective Date:	March 7, 2011
Unit Code:	4230
Additional Information:	This test will be discontinued. The recommended alternative is 40187 <i>Helicobacter pylori</i> Antibodies (IgG,IgA,IgM), EIA.

***Helicobacter pylori* IgG, IgA and IgM Antibody Reflex Panel, ELISA**

Effective Date:	March 7, 2011
Unit Code:	4830
Additional Information:	This test will be discontinued. The recommended alternative is 40324 <i>Helicobacter pylori</i> Antibody (IgG), EIA With Reflex to Blot.

Herpes Simplex Virus (HSV) 1/2 Antibody, ACIF (CSF)

Effective Date:	March 21, 2011
Unit Code:	60524
Additional Information:	This test will be discontinued. The recommended alternative is 60555 Herpes Simplex Virus 1/2 (IgG) Type-specific Antibodies, CSF.

Meningitis (Aseptic) Panel (CSF)

Effective Date:	March 21, 2011
Unit Code:	6036
Additional Information:	<p>This test will be discontinued. Please order the following individual tests as a replacement:</p> <p>60335 Coxsackie B (1-6) Antibodies, CSF</p> <p>60435 Echovirus Antibodies, CSF</p> <p>60555 Herpes Simplex Virus 1/2 (IgG) Type-specific Antibodies, CSF</p> <p>60545 Herpes Simplex Virus (HSV) 1/2 IgM Antibody, IFA (CSF)</p> <p>60625 Lymphocytic Choriomeningitis (LCM) Virus Ab, IFA (CSF)</p> <p>60712 Mumps Antibody Panel, IFA (CSF)</p>



DISCONTINUED TESTS

Meningoencephalitis Comprehensive Panel (CSF)	
Effective Date:	March 21, 2011
Unit Code:	6030
Additional Information:	This test will be discontinued. The recommended alternative is 6031 Meningoencephalitis Comprehensive Panel (CSF).

TORCH IgG and IgM Antibody Panel (CSF)	
Effective Date:	March 21, 2011
Unit Code:	1095
Additional Information:	<p>This test will be discontinued. Please order the following individual tests as a replacement:</p> <p>60923 <i>Toxoplasma gondii</i> IgG, ELISA (CSF) 60924 <i>Toxoplasma gondii</i> IgM, ELISA (CSF) 64600 Cytomegalovirus (CMV) IgG Antibody, ELISA (CSF) 64605 Cytomegalovirus (CMV) IgM Antibody, ELISA (CSF) 60555 Herpes Simplex Virus 1/2 (IgG) Type-specific Antibodies, CSF 60545 Herpes Simplex Virus (HSV) 1/2 IgM Antibody, IFA (CSF) 60880 Rubella IgG Antibody, ELISA (CSF) 60885 Rubella IgM Antibody, ELISA (CSF)</p>

TORCH Panel IgG Antibody (CSF)	
Effective Date:	March 21, 2011
Unit Code:	1096
Additional Information:	<p>This test will be discontinued. Please order the following individual tests as a replacement:</p> <p>60923 <i>Toxoplasma gondii</i> IgG, ELISA (CSF) 64600 Cytomegalovirus (CMV) IgG Antibody, ELISA (CSF) 60555 Herpes Simplex Virus 1/2 (IgG) Type-specific Antibodies, CSF 60880 Rubella IgG Antibody, ELISA (CSF)</p>

For questions or additional information, please contact the Focus Diagnostics Client Services Department at (800) 445-4032. Visit our web site at www.focusdx.com for a listing of new tests and test updates.